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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,966	05/10/2001	Rima Kaddurah-Daouk	AVZ-020CN	5588

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LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

EXAMINER

KIM, VICKIE Y

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 11/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/852,966

Applicant(s)

KADDURAH-DAOUK, RIMA

Examiner

Vickie Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10,68,72,73 and 75-88 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 10,68,72,73 and 75-88 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

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DETAILED ACTION

Status of Application

1. Acknowledgement is made of amendment filed 07/12/2003. Upon entering the amendment, the claims 68-70, 72 and 73 are amended and the claims 71 and 74 are canceled.
2. The claims 68-70, 72-73 and 75-88 are pending and presented for the examination.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 68-70, 75-80 and 84-85 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaddurah-Daouk et al(WO9614063).

Kaddurah-Daouk et al(WO'063 hereafter) teach a treatment of diseases of the nervous system comprising administering creatine or its salts to the subject wherein creatine compounds(creatine or its salts) are used for modifying energy of cells in stress via increasing energy reserve, sustaining energy production and modulating energy flow, see abstract and claims, especially page 39, line 8- page 40, line 9 and claim 4. WO'063 teaches various routes of administration including oral and topical application and dosage regimen, see page 33, lines 1-14. WO'063 teaches enhancement of therapeutic efficacy by co-administering

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beneficial secondary additives such as Q10 or nicotinamide that attenuate ATP depletion produced by malonate in vivo, see page 42, lines 7-13. WO'063 also teaches a secondary additives such as vitamins, see page 33, line 21.

Although, WO'063 is silent about energy of skin cell, it is inherently possessed feature where the intracellular energy metabolism in skin cell is modified by creatine supplement because creatine is also found in skin cell as well as brain, heart and muscle cells that is conventionally known knowledge* at the time of the invention was made(*see PTO-892 for the evidence). Furthermore, WO'063 also acknowledges that the creatine kinase(CK) is located near the sites in cells where energy generation occurs and the cells require energy to survive and to carry out the multitude of tasks that characterize biological activity, see page 34, lines 1-19. It is readily apparent to any skilled artisan that the energy level modification by creatine supplement is not limited to the only brain, muscle or heart cells but any cells that are associated with creatine kinase/creatine phosphate energy system. Thus, one would have readily envisaged that the modification of intercellular energy (e.g. increasing energy reserve, sustaining energy production and modulating energy flow) in the skin cell is naturally occurring when the creatine supplement is administered.

Thus, the claimed subject matter is not considered to be novel and not patentably distinct over the prior art of the record.

5. Claims 68-70, 75-76 and 84-86 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaddurah-Daouk et al(US 5,321,030).

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Kaddurah-Daouk et al(US'030 hereafter) teach a creatine(or its salts) and it's use as an antiviral agent for treating various diseases associated with variety of viruses via modifying energy level on the cells (e.g. increasing energy reserve, sustaining energy production and modulating energy flow), see abstract and column 7, lines 20-28 and lines 47-62. US'030 teaches various routes of administration including oral and topical application and dosage regimen, see column 20. WO'063 teaches enhancement of therapeutic efficacy by co-administering beneficial secondary additives such as antioxidant, see column 20, lines 68.

Most importantly, US'030 teaches the treatment of various diseases that involves skin infection such as vaginitis, vesicular stomatits, etc. US'030 contemplates the successful treatment of vaginitis achieved by topical application(i.e. cream) of creatine compounds. It also indirectly teaches skin cell involvement by testing cell originated facial vesicles, see example 1, at column 21 and column 32, lines 60. It is well known to the skilled artisan that Herpes simplex type I(HSV-1) virus or vesicular stomatitis virus causes vesicular eruptions on skin membranes(e.g. cold sores/fever blisters on lips or feet, respectively). From the teaching of US'030, one would have readily envisaged the modification of intercellular energy (e.g. increasing energy reserve, sustaining energy production and modulating energy flow) in the skin cell that is naturally occurring when the creatine supplement is administered. Thus, it is readily apparent to the skilled artisan that creatine supplement modulates cellular energy

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level of the skin cells to treat the viral infection on vaginal/genital area and facial area.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 68-70, 75-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greff(FR 2725896, abstract) and/or Courtin(FR 2734721, abstract) in view of Kaddurah-Daouk et al(US 5,321,030 or WO9614063).

Greff(FR'896 hereafter) teaches a cosmetic preparations for treating skin wrinkles wherein the treatment is associated with phosphocreatine synthesis using amino acids or precursor of amino acids that is necessary for creatin synthesis, see abstract.

Courtin(FR'721 hereafter) teaches a cosmetic preparation and its use in the treatment of skin aging and wrinkle prevention due to sunlight using vita-creatine(precursor of phosphocreatine), see abstract.

Applicant's claims differ because they require creatine(or its salts).

However, it would have been obvious to one of ordinary skill in the art to substitute amino acids or precursor of amino acids(FR'896) or vita-creatine(FR'721) with creatine(or its salts) when Greff and/or Courtin is taken in

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view of Kaddurah-Daouk et al(US'030 or WO'063) because each Kaddurah-Daouk et al 's patent teaches creatine supplement as being a phosphocreatine precursor in vivo, see col.5, lines 64-68(US'030) or page 1, lines 5-10(WO'063).

One would have been motivated to make such substitution because creatine is easy to obtain and is proven for its efficacy and safety as being a effective precursor for phosphocreatine in vivo.

It is noted again that the modification of cellular energy level via increasing energy reserve, sustaining energy production and modulating energy flow is inherently possessed feature where the intracellular energy metabolism in skin cell is modified by creatine supplement because creatine is also found in skin cell as well as brain, heart and muscle cells as mentioned above in 102 rejection(supra).

Thus, one would have been motivated to do so, with reasonable expectation of success, because it is always desirable to extend the therapeutic modalities to enhance the quality of the treatment(e.g.cost reduction, improvement of effectiveness) and patient compliance that would give more choices to the users(e.g. individualized based on needs and preference). Additionally the techniques and skills are well within the skilled level of the artisan having ordinary skill as suggested by the cited references.

As to the claims 75-88, each patent teaches the critical elements required by the instant dependent claims as mentioned above in 102 and 103 rejection. Thus, the claims are properly included in this rejection.

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As to the claims 72-73, where applicant requires creatine monohydrate or citrate as the effective species of the creatine salt, it is readily envisaged to skilled artisan that creatine monohydrate or creatine citrate is encompassed by the teaching, that is the pharmaceutically acceptable salts of creatine that is suggested by US030 or WO'063 because it is conventional knowledge* that creatine monohydrate or creatine citrate is pharmacologically effective creatine salts due to same pharmacore(responsible for th therapeutic effects), absent evidence to the contrary, see claim 1 (US'030) & claim 4(WO'063), and PTO-892*.

All the claimed subject matters are not considered to be patentably distinct over the prior art of the record.

Thus, all the claims are properly included in this rejection.

Double Patenting

8. Double patenting rejection is maintained due to the reasons of the record(see paper no.10). As requested by applicant in their response(see at page 7 remark section, paper no.11), this issue will be discussed upon a finding of subject matter that is allowable.

Conclusion

9. No claim is allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.**

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See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Vickie Kim,
Primary Patent Examiner
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